

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

SMITH &amp; NEPHEW, INC.

Plaintiff,

V.

INTERLACE MEDICAL, INC.

Defendant.

CIVIL ACTION  
NO. 1:10-cv-10951-RWZ

**DEFENDANT INTERLACE MEDICAL, INC.'S  
RESPONSIVE MARKMAN BRIEF (REDACTED)**

**TABLE OF CONTENTS**

I. BACKGROUND..... 1

    A. Interlace’s Accused Tissue Removal Device..... 1

    B. Overview of the Patent-in-Suit..... 2

II. PRINCIPLES OF CLAIM CONSTRUCTION ..... 3

III. ARGUMENT ..... 4

    A. “a drive coupled to the cutting member to simultaneously rotate,  
        translate, and reciprocate the cutting member in response to only a  
        rotational force applied to the drive in a single direction” ..... 4

        1. The Term “Drive” Is A Means-Plus-Function Element Subject  
            To 35 U.S.C. § 112 ¶ 6..... 5

        2. If The “Drive” Is Not Subject To § 112 ¶ 6, Then It Must Be  
            Construed Consistent With The Record ..... 10

            a. The drive must be a “single mechanism”..... 10

            b. The drive must also directly transfer the applied rotational  
                force ..... 12

    B. “drive member attached to the cutting member” ..... 13

    C. “cutting window” ..... 15

    D. “translation piece” ..... 17

    E. “coupled” ..... 19

    F. “arched bridge shape” ..... 20

    G. “chamfered cutting edge” ..... 20

## TABLE OF AUTHORITIES

### CASES

<i>Acco Brands, Inc. v. America Power Conversion Corp.</i> , 2003 U.S. Dist. LEXIS 27829 (E.D. Tex. July 16, 2003) .....	9
<i>Aspex Eyewear, Inc. v. Altair Eyewear, Inc.</i> , 288 Fed. Appx. 697 (Fed. Cir. 2008) .....	6
<i>Bicon, Inc. v. Straumann Co.</i> , 441 F.3d 945 (Fed. Cir. 2006) .....	15
<i>Bradford Co. v. Conteyor N. America, Inc.</i> , 603 F.3d 1262 (Fed. Cir. 2010) .....	19-20
<i>Haney v. Timesavers, Inc.</i> , 1995 U.S. App. LEXIS 2535 (Fed. Cir. Feb. 10, 1995) .....	9
<i>Linear Technology Corp. v. Impala Linear Corp.</i> , 379 F.3d 1311 (Fed. Cir. 2004) .....	8
<i>M.I.T. v. Abacus Software</i> , 462 F.3d 1344 (Fed. Cir. 2006) .....	5
<i>Markman v. Westview Instruments, Inc.</i> , 52 F.3d 967 (Fed. Cir. 1995) .....	4
<i>Mas-Hamilton Group v. LaGard, Inc.</i> , 156 F.3d 1206 (Fed. Cir. 1998) .....	6, 7, 9
<i>Multiform Desiccants, Inc. v. Medzam, Ltd.</i> , 133 F.3d 1473 (Fed. Cir. 1998) .....	4
<i>Nystrom v. Trex Co.</i> , 424 F.3d 1136 (Fed. Cir. 2005) .....	3
<i>O2 Micro International Ltd. v. Beyond Innovation Technology Co.</i> , 521 F.3d 1351 (Fed. Cir. 2008) .....	14
<i>O.I. Corp. v. Tekmar Co., Inc.</i> , 115 F.3d 1576 (Fed. Cir. 1997) .....	14
<i>Omega Engr., Inc. v. Raytek Corp.</i> , 334 F.3d 1314 (Fed. Cir. 2003) .....	12

<i>PACid Group, LLC v. Apple, Inc.</i> , 2010 U.S. Dist. LEXIS 70997 (E.D. Tex. July 15, 2010).....	14
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005) .....	3, 4, 14
<i>St. Jude Medical, Inc. v. Access Closure, Inc.</i> , 2010 U.S. Dist. LEXIS 82221 (W.D. Ark. July 19, 2010).....	6
<i>In re Translogic Technology, Inc.</i> , 504 F.3d 1249 (Fed. Cir. 2007) .....	20
<i>Vitronics Corp. v. Conceptronic, Inc.</i> , 90 F.3d 1576 (Fed. Cir. 1996) .....	4
<i>Welker Bearing Co. v. PHD, Inc.</i> , 550 F.3d 1090 (Fed. Cir. 2008) .....	6
<i>Widevine Technologies, Inc. v. Verimatrix, Inc.</i> , 2009 U.S. Dist. LEXIS 102768, 2009 WL 3734106 (E.D. Tex. Nov. 4, 2009).....	6

## STATUTES

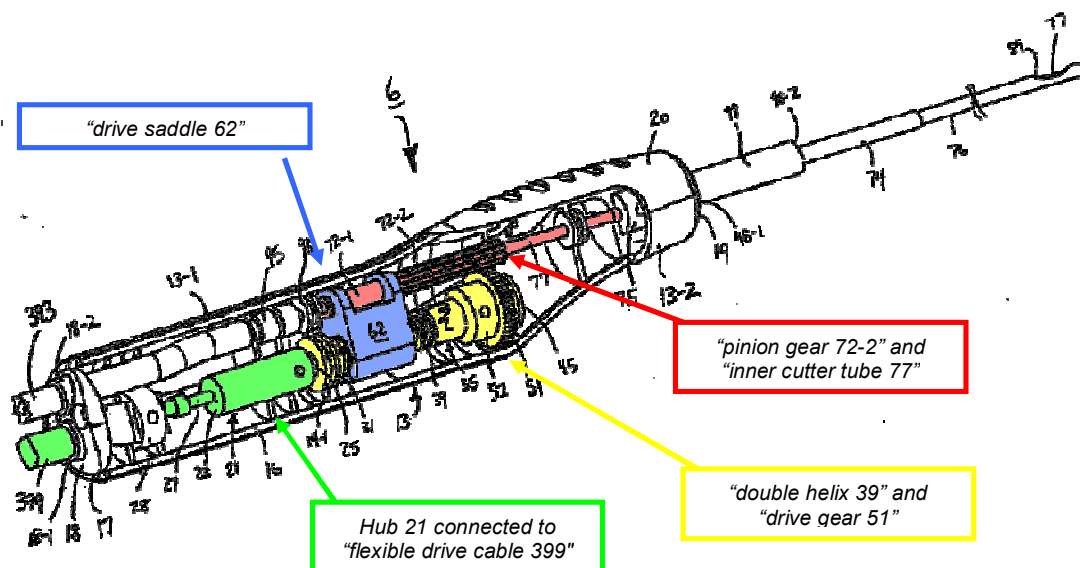
35 U.S.C. § 112 ¶ 6.....	passim
--------------------------	--------

Defendant, Interlace Medical, Inc. (“Interlace”), respectfully submits this brief in support of its proposed construction of certain terms of U.S. Patent No. 7,226,459 (‘the ‘459 patent’). Plaintiff Smith & Nephew’s (“S&N’s”) proposed claim constructions are fundamentally at odds with the claim language and the intrinsic evidence, particularly the file history. Indeed, it is remarkable that S&N virtually ignores the file history given that such evidence was the centerpiece of Interlace’s arguments in its Motion For Preliminary Injunction. Interlace’s constructions comport with this evidence. To assist the Court in understanding the parties’ claim construction disputes, it is helpful to briefly discuss the accused Interlace device.

## I. BACKGROUND

### A. Interlace’s Accused Tissue Removal Device

Interlace is a medical device company based in Framingham, focused on developing devices for the interventional gynecologist to perform procedures in-office as opposed to the operating room. (*See* D.N. 12 ¶ 2.) It recently launched a state-of-the-art “Tissue Removal Device” (“TRD”), which is currently the only device for removal of uterine fibroids in women that has been FDA-cleared for use in a doctor’s office on an outpatient basis. The basic structure of Interlace’s accused TRD – a device that is a fundamental departure from the claims of the ‘459 patent – is shown in the schematic cross-section below:

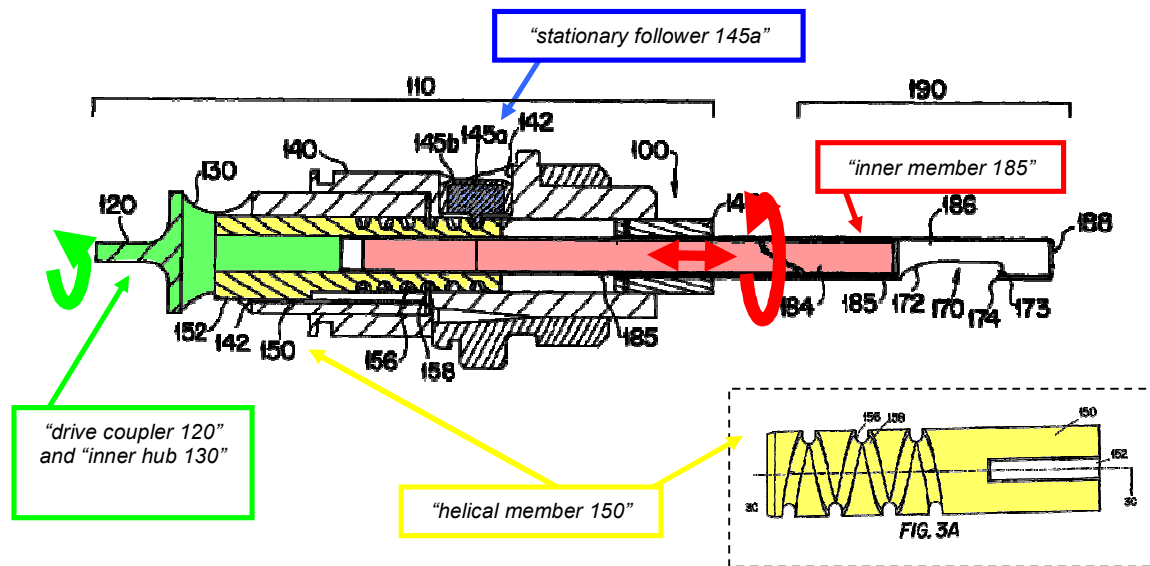


(*Id.* ¶ 6.) The rotation of the yellow drive gear 51 engages with red pinion gear 72-2, which in turn causes rotation of the cutter tube 77 (also red). (*Id.*) Thus, the drive gear transmits a rotational force – rather than a translational force – to the cutter tube. The reciprocating motion of the cutting member is achieved through a separate mechanism, *i.e.*, by interaction of the saddle 62 (blue) and the helical groove of the double helix 39. (*Id.*) As the helix rotates, the saddle slides back and forth in the groove. (*Id.*) Because the saddle is connected to the red cutter tube, the reciprocation of the saddle causes reciprocation of the cutter. (*Id.*) The saddle thus transmits a translational force – rather than a rotational force – to the cutter tube. (*Id.*)

### **B. Overview of the Patent-in-Suit**

The ‘459 patent is generally directed to a surgical instrument for cutting semi-rigid tissue. Such devices have been around for more than 10 years and been used in a very wide range of medical applications. The claims of the ‘459 patent are generally directed to rotary surgical devices that have cutters that rotate and translate in a reciprocating manner as shown, for example, in Figure 10 of the ‘459 patent. (*See Ex. A.*) The tissue cutting is performed by a cutting member (185), which is a hollow tube with a sharpened edge, together with the cutting window (170). The cutting member reciprocates back and forth within an outer tube (186) that has a cutting window (170) in its side. When the cutting window is placed over tissue, the cutting member slides across the cutting window, and the member and window together cut tissue within the window.

All of the asserted claims require a “drive coupled to the cutting member to simultaneously rotate, translate, and reciprocate the cutting member in response to only a rotational force applied to the drive in a single direction” (the “exclusive rotational force” limitation). Such a device is shown in Figure 1 of the ‘459 patent, as annotated below:



A rotational force is applied to a drive hub 120 (green) from an external motor or similar source of rotation. (*See* Ex. A col. 3:20 – col. 4:22.) Coupled to the drive hub through a key-and-slot arrangement is a “helical member” (yellow). (*Id.*) The helical member is so called because it contains a double-helical groove cut into its side, as shown in Figure 3A (also above). This groove is engaged by a “translation piece” (blue) fastened to the main housing of the device. (*Id.*) As the helical member turns, the stationary member causes the helical member to move back and forth axially. (*Id.*) **Only** a rotational force is applied to the drive hub and this force causes both rotation and reciprocation of the helical member and, in turn, the cutting member, which is attached to the helical member.

## II. PRINCIPLES OF CLAIM CONSTRUCTION

Tellingly, S&N presents an incomplete description of the governing principles of claim construction, particularly the relative importance of the intrinsic record (including claim language, the specification and file history) versus extrinsic evidence (such as dictionary definitions). Of greatest import, S&N largely ignores the importance of the specification and file history. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). The claims must be read in the context of the entire patent, including the specification and the file history. *Id.* at 1315; *Nystrom v. Trex Co.*, 424 F.3d 1136, 1142 (Fed. Cir. 2005) (“[T]he claim terms ‘must be read in view of the specification, of which they are a part.’”) (quoting *Markman v.*

*Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995)); *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1478 (Fed. Cir. 1998) (“The best source for understanding a technical term is the specification from which it arose, informed, as needed, by the prosecution history.”); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (“Usually [the specification] is dispositive; it is the single best guide to the meaning of a disputed term.”).

S&N also fails to recognize the limited role that extrinsic evidence, particularly dictionary definitions, should play in a modern claim construction analysis. *See Phillips*, 415 F.3d at 1318-19, 1321-22. *Phillips* warned against undue reliance on dictionary definitions, overturning the *Texas Digital* line of cases, which considered dictionary definitions to be of primary importance rather than the specification or file history. *Id.* at 1319.

### III. ARGUMENT

#### A. “a drive coupled to the cutting member to simultaneously rotate, translate, and reciprocate the cutting member in response to only a rotational force applied to the drive in a single direction”

Interlace’s Proposed Claim Construction	S&N’s Proposed Claim Construction
<p>This claim element is a means-plus-function claim governed by 35 U.S.C. §112 ¶ 6.</p> <p><i>Function</i>: “simultaneously rotate, translate, and reciprocate the cutting member in response to only a rotational force applied to the drive in a single direction”</p> <p><i>Structure</i>: the inner hub 130, having at one end the drive coupler 120, the helical (or drive) member 150, and the translational piece 145</p> <p>If the claim element is not governed by 35 U.S.C. §112 ¶6, then Interlace would propose the following construction: “a single mechanism that converts an applied rotational force in a single direction into reciprocating and translating forces on the cutting member and that directly transfers the applied rotational force to the cutting member”</p>	<p>“all components between (a) a motor/power source and (b) a cutting component having a cutting element, such that the cutting component simultaneously (i) rotates, (ii) translates, and (iii) reciprocates in response to a rotary motion being applied in a single direction to one of the components between (a) and (b)”</p> <p>where “drive” means “all components between a motor/power source and a load”</p>



In the course of the prosecution of the ‘459 patent, the Examiner was faced with extraordinarily close prior art, with the Examiner selecting the Glatzer patent as a representative example of this art. After an extended discussion about specifics of invention in light of Glatzer and other references, the Examiner granted the claim. A review of this colloquy between the PTO and the patentee in light of the similarity of the art suggests that allowance must have resulted from one of two conclusions reached by the Examiner: (1) the “drive” limitation was understood as a means-plus-function claim, and therefore limited to the structure in the specification, or (2) “drive” was understood to be a structural limitation that was circumscribed in scope by the description in the specification. While it is unclear which of these understandings led the Examiner to allow the claim, it is unambiguous that the claim was only allowed in light of a very narrow view of the “drive” claim limitation.

Remarkably, despite the fact that the prosecution history and the Glatzer patent were the centerpiece of Interlace’s Motion For Preliminary Injunction, and was discussed extensively at the hearing on that motion, S&N’s brief *does not even mention the Glatzer prior art reference*. In light of this failure – an obvious effort to prevent Interlace from providing a written response to S&N’s arguments regarding Glatzer – Interlace respectfully asks the Court to consider any such arguments in S&N’s reply brief with appropriate skepticism.

**1. The Term “Drive” Is A Means-Plus-Function Element  
Subject To 35 U.S.C. § 112 ¶ 6**

The asserted claims require a “drive” coupled to the cutting member for performing the function recited in the claim. The word “drive” has no structural connotation in the claim; it could just as easily be substituted with “means,” “mechanism,” “device,” “element” or any other term for generic structure that performs a specified function. S&N acknowledges that such terms are means-plus-function elements governed by 35 U.S.C. § 112 ¶ 6 even though they do not use the word “means.” *See M.I.T. v. Abacus Software*, 462 F.3d 1344, 1354 (Fed. Cir. 2006) (“colorant selection mechanism” was generic and subject to § 112 ¶ 6; “a limitation lacking the term ‘means’ may overcome the presumption against means-plus-function treatment if it is

shown that ‘the claim term fails to ‘recite sufficiently definite structure’ or else recites ‘function without reciting sufficient structure for performing that function.’”) (internal quotation marks omitted); *see also Welker Bearing Co. v. PHD, Inc.*, 550 F.3d 1090, 1096 (Fed. Cir. 2008) (the “mechanism for moving said finger” is a means-plus-function term).

While S&N will argue that a “drive” is a kind of structure, the Federal Circuit has held that “the question is not whether [the claim elements at issue] are physical structures but whether they are **sufficiently definite** structures.” *Aspex Eyewear, Inc. v. Altair Eyewear, Inc.*, 288 Fed. Appx. 697, 703 (Fed. Cir. 2008) (holding that “retaining mechanisms” were not “sufficiently definite” structure and were subject to § 112 ¶ 6);<sup>1</sup> *Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206, 1214 (Fed. Cir. 1998) (“In the instant case, the claimed ‘lever moving element’ is described in terms of its function not its mechanical structure.”)); *see also Widevine Techs., Inc. v. Verimatrix, Inc.*, Civil Action No. 2-07-cv-321, 2009 U.S. Dist. LEXIS 102768, 2009 WL 3734106, at \*14 (E.D. Tex. Nov. 4, 2009) (holding that “first device” and “second device” were means-plus-function limitations since the “claim provides no structural context and describes each ‘device’ by the functions that it performs”); *St. Jude Med., Inc. v. Access Closure, Inc.*, No. 4:08-cv-04101-HFB, 2010 U.S. Dist. LEXIS 82221, at \*66 (W.D. Ark. July 19, 2010) (“As used in the “ejecting mechanism” term, the word “ejecting” is purely functional stating only the function of the ‘mechanism.’”).

The term “drive” is clearly a generic structural element, as confirmed by the testimony of the inventors (all accomplished engineers) and prosecution counsel (Ph.D. in physics) of the ‘459 patent. These witnesses testified that the “drive” was **“any structure,” “any mechanism,” or “anything”** for performing the claimed function. For example, Ms. Drucker agreed that a drive was “  
.” (Ex. B at 80:16-21.)

Mr. Cesarini also testified that “

---

<sup>1</sup> In this brief, emphasis is added unless otherwise indicated.

” (Ex. C at 88:11 – 89:3.) Mr. Jezierski agreed that “

” (Ex. D at

41:2-22.)<sup>2</sup> S&N’s prosecution counsel agreed that the drive “would have been any structure that performs that function described in the claim.” (Ex. F at 41:23 – 42:25; *see also* 47:9-24 (agreeing that “  
”).)

Under governing Federal Circuit case law, the fact that “drive” refers to “any structure” or “any mechanism” for performing the claimed function establishes that the “drive” is a generic structural term subject to § 112 ¶ 6. Indeed, in *Mas-Hamilton Group*, the Federal Circuit applied § 112 ¶ 6 to a claim limitation that did not recite “means” because otherwise the claim would cover any structure for performing the claimed function:

If we accepted La Gard’s argument that we should not apply section 112, P 6, a “moving element” could be any device that can cause the lever to move. La Gard’s claim, however, cannot be construed so broadly to cover every conceivable way or means to perform the function of moving a lever, and there is no structure recited in the limitation that would save it from application of section 112, P 6.

156 F.3d 1206, 1214 (Fed. Cir. 1998). In this case, the inventors and prosecution counsel establish that the word “drive” refers to any structure that performs the function of rotating and reciprocating the cutting blade. Thus, § 112 ¶ 6 must apply.

S&N’s expert, Mr. Hogan, does not opine to the contrary. Instead, he says only that the terms “drive” and “mechanism” have different meanings, a proposition that is irrelevant to whether “drive” is generic. Indeed, while S&N acknowledges (Br. at 9) that the Federal Circuit has held that “mechanism” is a generic structural term subject to § 112 ¶ 6, Mr. Hogan suggests that the term **“drive” may be even more generic than “mechanism.”** (D.N. 29 ¶ 20 (“A

---

<sup>2</sup> The fourth inventor, Mr. Cassidy, regarding the meaning of “drive.” (Ex. F 10:8-24.)

and had no opinions

mechanism may be a component of a drive, but not all drives are mechanisms....”).) If the term “drive” refers to an even broader group of structures than “mechanism,” which is considered to be generic by the Federal Circuit and subject to § 112 ¶ 6, then the term “drive” must also be generic and subject to § 112 ¶ 6.

Mr. Hogan’s opinion on the meaning of drive – “a system or assemblage of components configured so as to enable the transfer of power from a power source ... to a power sink or load....” (D.N. 29 ¶ 17) – actually supports Interlace’s argument because his definition is hopelessly generic. The claimed function in the ‘459 patent necessarily involves the transfer of power from a source to a load. Thus, Mr. Hogan’s understanding of a “drive” amounts to nothing more than “a system or assemblage of components” for performing that function. S&N’s proposed construction of “drive” supports the application of § 112 ¶ 6 for the same reasons. According to S&N, the “drive” is simply “all components” between a power source and a load that perform the claimed function. Because the claimed function is nothing more than transferring power (only a rotational force in a single direction) to a cutting element (a load), there is no difference between a “means” for performing the function or “all components” for performing the function, as S&N proposes. S&N’s construction places no limit on the kind of “components” that comprise the drive.<sup>3</sup>

Finally, S&N’s reliance on two cases regarding electronic “circuits” and a “double-drive mechanism” do not undermine the generic nature of “drive” in the ‘459 patent. An electronic circuit is a specific kind of structure, involving only electronic components. *Linear Tech. Corp. v. Impala Linear Corp.*, 379 F.3d 1311, 1320 (Fed. Cir. 2004) (“[W]hen the structure-connoting term ‘circuit’ is coupled with a description of the circuit’s operation, sufficient structural meaning generally will be conveyed to persons of ordinary skill in the art”). A “double-drive mechanism interposed between a platen and frame” was also found to be a specific kind of structure known in the art. Such a structure had to employ the “double-drive” architecture

---

<sup>3</sup> Similarly, the dictionaries relied on by S&N do not provide any description of a structure other than “all components” that transfer power from a source to a load.

known in the mechanical arts. *See Haney v. Timesavers, Inc.*, 1995 U.S. App. LEXIS 2535, at \*7-8 (Fed. Cir. Feb. 10, 1995) (“The clause ‘a double-drive mechanism interposed between and connecting the platen and frame’ recites structure. This recitation of structure in concert with accompanying function – ‘where the double-drive mechanism imparts at least one translational orbital movement superimposed on another movement to the platen relative to the frame’ – removes the claim from the purview of § 112, paragraph 6.”). Thus, the “double drive” was specific in the sense that “rack and pinion” is a specific structure used, for example, in an automobile steering mechanism. *See Acco Brands, Inc. v. Am. Power Conversion Corp.*, No. 2:02-cv-113-TJW, 2003 U.S. Dist. LEXIS 27829, at \*16 (E.D. Tex. July 16, 2003).

In this case, by contrast, S&N contends the term “drive” refers to any group of “components” that transfers force from a source to a load. There is no requirement that these components be electrical, as in *Linear*. And there is no requirement that the components be organized in a specific arrangement, like the “double drive” described in *Haney*. The “drive” in the ‘459 patent is, as S&N acknowledges, simply any group of components for performing the claimed function. This is a quintessential example of a generic structure subject to § 112 ¶ 6.

Under § 112 ¶ 6, interpretation of the “drive” element is straightforward. The Court must identify the function of the claim element as well as the structure described in the specification that corresponds to the claimed function. *Mas-Hamilton*, 156 F.3d at 1211. S&N does not appear to dispute Interlace’s proposed construction under § 112 ¶ 6. The function of the “drive” element is set forth in the claim: “to simultaneously rotate, translate, and reciprocate the cutting member in response to only a rotational force applied to the drive in a single direction.” The corresponding structure in the specification has already been identified by S&N in its opposition to Interlace’s Motion for Preliminary Injunction as the inner hub 130, having at one end the drive coupler 120, the helical (or drive) member 150, and the translational piece 145. (*See S&N’s Opp. To Mot. For Preliminary Injunction* at 3.)

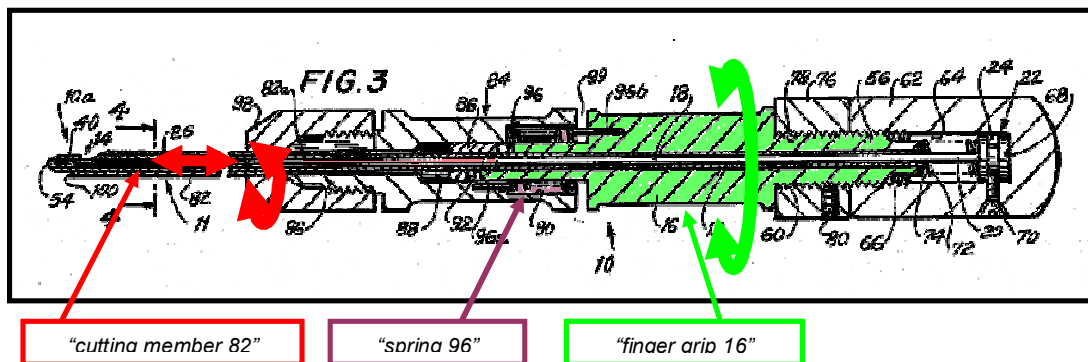
**2. If The “Drive” Is Not Subject To § 112 ¶ 6, Then It Must Be Construed Consistently With The Record**

If the Court believes that the claimed “drive” is not a generic structure but instead a specific structure, and thus not subject to § 112 ¶ 6, it should construe that structure consistently with the intrinsic evidence. S&N’s overbroad proposed construction of the exclusive rotational force limitation – required in order to assert infringement – runs directly contrary to statements S&N made to the Patent Office in order to get the patent issued. If the “drive” is to be understood as a structural element, the intrinsic evidence provides that the “drive” is (i) a single mechanism that converts an applied rotational force in a single direction into reciprocating and translating forces on the cutting member and (ii) that directly transfers the applied rotational force to the cutting member.

**a. The drive must be a “single mechanism”**

In the Office Action dated September 17, 2004, the Patent Office rejected claim 1 over U.S. Patent No. 5,425,376 to Banys. (Ex. G.) In response, S&N amended Claim 1, adding the term “reciprocate,” which had previously not appeared in the claim. (Ex. H.) S&N also submitted arguments in support of the patentability of Claim 1 over the Banys patent, asserting that Banys “fails to describe or suggest a drive coupled to a cutting member to cut tissue during simultaneous rotation and translation of the cutting member *in response to only a rotational force applied to the drive.*” (*Id.*) The bolded language was amended to the claims.

In response, the Patent Office again rejected Claim 1, this time in light of U.S. Patent No. 3,995,619 to Glatzer. (Ex. I) Glatzer’s Figure 3 is reproduced below with annotations:



(Ex. J.) In prosecution, S&N explained its understanding of the device in Glatzer, a device remarkably similar to that of the '459 patent:

Glatzer relates to an instrument having a cutter element 82, and a cutter actuator 84 coupled to the cutter element 82 and mounted on a grip 16 for driving the cutter element 82... The cutter actuator 84 includes a cavity 90 that houses a spring 96 having a leg 96a received within the cutter actuator 84 and a leg 96b received within the grip 16.... The cutter actuator also includes a screw 94 that is received within a helical groove 92 of an extension 86 of the grip 16.

(Ex. K p. 7.) The patentee described how the cutter rotated and reciprocated in Glatzer:

A user turns the cutter actuator 84 relative to the grip 16 and against the spring and torsional forces of the spring 96.... As Glatzer explains “[a]ngular displacement [*i.e.* rotation] of the cutter actuator 84 [sic] against the action of the helical spring 96 causes simultaneous linear translation or movement of the cutter actuator 84 in a direction away from the finger grip 16” and such axial advancement of the cutter actuator 84 causes axial advancement of the cutter element 82.

(*Id.* pp. 7-8.) When the finger grip 16 is released, the stored energy in the spring 96 causes the proximal movement and rotation of the cutter. (*Id.*; *see also* Ex. J col. 14:2-5; Ex. P pp. 7-8.)

Importantly, only a rotational force is applied to the grip to cause the reciprocation and rotation of the cutter – the user rotates the grip, then lets go. The lead inventor, Mr. Cesarini explained this reciprocating action: (1) the user provides a rotational force to the handle, which translates the cutter head distally and rotates the cutter head at the same time; (2) then the grip is released and the handle rotates back and the cutter element contracts proximally and rotates.

(Ex. C at 102:3-17.) Importantly, “when the user releases the handle, they’re not applying any force to the handle because it’s released.” (*Id.* at 102:18-21.)

S&N distinguished the exclusive rotational force limitation from Glatzer in response to the Patent Office’s rejection. It explained that:

[T]he cutter element [in Glatzer] rotates and translates proximally in response to both a rotational force (the torsional force of the spring 96) and an axial or translational force (the axial spring force of the spring 96). Glatzer’s cutter element 82 does not reciprocate in response to only a rotational force.

(Ex. K p. 8.)

It is undisputed that, in Glatzer, all of the energy for rotating and reciprocating the cutter member comes from the same rotational source, *i.e.*, rotation of the finger grip 16. (Ex. C at 102:14 – 103:14.) Yet, by defining the “drive” in a manner that excluded Glatzer, S&N established that the claimed “drive” was narrower than simply applying only a rotational force to some component of the device. In other words, S&N told the PTO that the claims do not necessarily cover devices having a cutting member that is reciprocated by one mechanism and translated by another mechanism (like a spring), even if only a rotational force in a single direction has been applied, as in Glatzer. Thus, the prosecution history mandates that the above-noted claim limitation excludes surgical devices in which the cutter element is provided with *different mechanisms* to achieve rotational *and* translational forces even if, ultimately, all of the energy for rotating and translating the cutter member comes from the same source. Here, however, S&N now proposes that the drive can include “all components” between the source and the cutting element for performing the claimed function, which would clearly cover Glatzer. S&N’s proposed construction is contradicted by the intrinsic evidence and should, therefore, be rejected. The intrinsic evidence supports Interlace’s construction that the “drive” must be at least “a single mechanism that converts an applied rotational force in a single direction into reciprocating and translating forces on the cutting member.”<sup>4</sup>

**b. The drive must also directly transfer the applied rotational force**

The prosecution history shows that the claimed drive cannot cover a device that includes one mechanism providing a rotational force to rotate a cutting member and another mechanism providing a translational force to translate the cutter member. Converting an applied rotational force into a translational force necessarily requires a mechanism to achieve the conversion of force; this is because the rotational forces are in a different direction than the translational forces.

---

<sup>4</sup> While Interlace believes that the patentee’s statements during prosecution provide a definition of the term “drive,” the arguments made to distinguish Glatzer could also be considered an intentional disclaimer of claim scope. *See, e.g., Omega Engr., Inc. v. Raytek Corp.*, 334 F.3d 1314, 1315 (Fed. Cir. 2003).



If the rotational forces were transferred to the cutting member through a separate mechanism, then the device would have two, separate mechanisms, which the file history shows to be outside the scope of the “drive.” Thus, the rotational energy must be directly applied to the cutting member. This is the only way the device can apply both translational and rotational forces to the cutter from only a rotational force through a single mechanism. This requirement follows directly from the statements in the file history distinguishing Glatzer.

This requirement is also supported by the specification. The only embodiments discussed in the specification involve direct application of rotational force to the cutting member. (*See, e.g.*, Ex. A Figure 1.) There is no description of any device that converts the applied rotational force into other rotational forces on the cutting member, *e.g.*, through gears. In fact, the specification only shows the cutting member attached directly to the helical member so that the rotational forces applied to the drive are transferred directly to the cutting member. In other words, if there were an indirect transfer of the rotational force, *e.g.*, through gears, then the rotational forces would be applied to the cutting member through two separate mechanisms, which the S&N told the Patent Office was not part of the drive.

**B. “drive member attached to the cutting member”**

Interlace’s Proposed Claim Construction	S&N’s Proposed Claim Construction
“a member of the drive that does not move relative to the cutting member”	<p>“a component of the drive connected to a component including a cutting element such that at least one degree of freedom is constrained between the two components”</p> <p>where “attached” means “a connection in which one component constrains at least one degree of freedom of another component”</p>

Interlace’s construction of “drive member attached to the cutting member” comes straight from the prosecution history. In response to an objection from the Patent Office, S&N distinguished Glatzer by asserting that Glatzer’s cutting element was not attached to a drive member. S&N expressly defined “attached” as meaning that the two components did not “move relative” to each other:

In Glatzer, the helical groove 92 is formed in the extension 86.... ***However, the extension 86 is not attached to the cutter element 82 of Glatzer's instrument 10. Rather, the extension 86 is attached to the grip 16, and the cutter element 82 and the actuator 84 move relative to the extension 86 and grip 16.*** Moreover, the only features of Glatzer's instrument 10 that are attached to the cutter element 82 are the actuator 84 and the screw 94, neither of which include a helical groove....

(Ex. K p. 8.) S&N said Glatzer's cutter was not attached to the extension because those elements would "move relative" to each other. This express definition of "attached" governs. *See Phillips*, 415 F.3d at 1316 . Thus, this claim term should be construed to mean "a drive member that does not move relative to the cutting member."

S&N asserts that Interlace's construction should be rejected because claim 10, which depends from claim 1, already requires that the drive member rotate and reciprocate with (*i.e.*, not move relative to) the cutting member. S&N's reliance on claim differentiation is unavailing. That doctrine is a tool of last resort for difficult claim interpretations, and it cannot be used to override clear definitions of claim terms in the intrinsic evidence, as is the case here. *O.I. Corp. v. Tekmar Co., Inc.*, 115 F.3d 1576, 1582 (Fed. Cir. 1997) (expressing the notion that there are practical limits to the doctrine of claim differentiation: "the doctrine cannot alter a definition that is otherwise clear from the claim language, description, and prosecution history."). Indeed, claim differentiation is particularly inapposite here, as the '459 patent contains some dependent claims that are redundant of other claims. (*See, e.g.*, Ex. C at 98:7-22 (claim 32 already entails claim 33).) The fact that claim 10 may be redundant of claim 1 should not preclude the Court from applying the correct interpretation of the "drive member attached to the cutting member" as expressly defined during prosecution of the '459 patent.<sup>5</sup>

---

<sup>5</sup> In addition, S&N's construction is unintelligible and would not serve to clarify the meaning of the claim to the jury. (*See PACid Group, LLC v. Apple, Inc.*, 2010 U.S. Dist. LEXIS 70997 (E.D. Tex. July 15, 2010) ("[I]t is appropriate to provide a construction that would assist a lay jury in understanding what a person of ordinary skill in the art would understand" the claim term to mean); *see also O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) ("[C]laim construction is a matter of resolution of disputed meanings and technical scope, **to clarify** and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement.")).

## C. “cutting window”

Interlace’s Proposed Claim Construction	S&N’s Proposed Claim Construction
“a window in the outer tubular member that has a sharpened edge for cutting tissue or holding tissue to be cut”	“an area to enable access to a cutting component”

S&N’s attempt to read the word “cutting” out of this claim element – so that “cutting window” would mean the same as “window” – should be rejected. *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) (“[C]laims are interpreted with an eye toward giving effect to all terms in the claim.”). The plain and ordinary meaning of the term “cutting window” is “a window that cuts.” This meaning is confirmed by the parties’ agreed upon construction with respect to the term “cutting member” – “a member that cuts tissue.” (See S&N’s Br. n. 1.) The use of the term “cutting” implies that the window actually cuts or is involved in cutting (*e.g.*, by holding tissue to be cut), not that the window merely exposes the tissue to a separate (and undefined) “cutting component,” as S&N proposes.

The patent further confirms Interlace’s proposed construction. The specification describes the edge of the cutting window (distal end 173) as being “chamfered to provide a sharp edge,” just like the cutting member. (Ex. A at 5:4-5, 5:18-20; *see also id.* at 5:1-10; 5:23-33.) Without a sharpened edge, the cutting window would not be able to hold or cut the tissue, which is its purpose. Mr. Cesarini, the lead inventor, generally defined cutting windows as “

” (Ex. C at 15:8-10.) In

discussing a prior art product, Mr. Cesarini stated that the “cutting window” is

. (*Id.* at

23:7-24; 35:15-24.) When specifically asked about claim 32 of the ‘459 patent, Mr. Cesarini confirmed that the “cutting window” is “

” (*Id.* at 97:1-10.) Mr. Cassidy, another inventor, also confirmed

” (Ex. F at 12:25

– 13:7.) Ms. Drucker confirmed that one of the purposes of the cutting window is to “

. (Ex. B at 51:2 – 53:9.)

The Invention Disclosure document produced by S&N describes the participation of the cutting window

(Ex. L at FR0000984.) Mr. Cesarini, testified that this “

. (Ex. C. at 79:22 – 81:2.) Thus, a “cutting window” as envisioned in the ‘459 patent must be able to cut tissue or hold the tissue to be cut.

During the prosecution of the ‘459 patent, the Examiner and S&N confirmed that a “cutting window” holds the tissue to be cut. For example, in rejecting certain claims in light of the prior art, the Examiner found numerous examples of “cutting windows” in the prior art. (*See* Ex. G pp. 3-4; *see also* Ex. I pp. 3-4.) The Examiner repeatedly stated that a “cutting window or opening” would “enhance tissue grabbing or tissue retention effectiveness.” (*See* Ex. G p. 4; *see also* Ex. I p. 3; Ex. O p. 3.) The Examiner further stated that the prior art “discloses that cutting windows can have various configurations, depending on the desired cutting edge and the desired degree of tissue grabbing.” (Ex. G p. 4.) Thus, the Examiner acknowledged a “cutting window” is not merely an opening to expose the tissue to the cutting member; rather, it cuts tissue or holds the tissue for cutting.

In discussing the Banys patent, the Examiner stated that Banys teaches a cutting window: “[l]ateral opening 28 is formed with at least one sharp cutting edge 27 near the distal end of opening 28, to assist in the cutting of a sample from the selected tissue.” (Ex. O pp. 3-4; Ex. M at 5:6-8.) Similarly, with respect to Glatzer, the S&N stated that “[i]n Glatzer, a cutting window is formed inside the cutter element 82 by the hollow tube hook 14, which is received within the cutter element 82.” (Ex. K p. 1.) “Thus, Glatzer’s instrument first grabs the suture within the hook 14 using the rod 18 and then cuts the suture with the cutter element 82, which passes over the hook 14.” (*Id.* at 10-11.)

S&N’s proposed construction suffers from numerous flaws. First, it introduces the new concept of a “cutting component” – such a term is not used in the claims. The proposed “cutting component” is ambiguous, is not helpful to understanding the term, and is unsupported by any intrinsic evidence. Second, the phrase “an area to enable access” is also vague. S&N provides a dictionary definition for the term “window” as an “opening,” but then changes that term – without support or rationale – to “area” in its proposed construction.

**D. “translation piece”**

Interlace’s Proposed Claim Construction	S&N’s Proposed Claim Construction
“a non-reciprocating piece of the drive that converts an applied rotational force into a translational force on the cutting member”	“a drive component located at least in part in a helical groove to enable simultaneous reciprocation, translation, and rotation of a drive member relative to this drive component when a rotary motion is applied to the drive in a single direction”

The term “translation piece” appears in claims 1, 8, 9, 19, 21, 22, 30, and 31, all of which depend from independent claims 1 and 30 and require that “the drive includes a *translation piece* disposed in the groove such that rotary driving of the drive member *results in simultaneous reciprocation of the drive member relative to the translation piece.*” The key disagreement between the parties is whether the translation piece can reciprocate. The claim language itself shows that *the drive member reciprocates*, not the translation piece. This interpretation is confirmed by the specification, in which the translation piece is located in a cutout in the non-moving outer hub, and it is the translation piece that causes the translation and reciprocation of the drive member. (*See* Ex. A col. 3:31-34; 4:18-22; 4:23-31; 4:36-43.)

S&N offers no support for its proposed construction. (S&N’s Br. at 16-17.) In fact, its attack on Interlace’s proposed construction relies upon a mischaracterization of the claim language. On page 17 of its brief, S&N argues that “[c]laim 1 expressly requires that the translation piece reciprocate relative to the drive member.” The claim provides, however, that “rotary driving of the drive member *results in simultaneous reciprocation of the drive member* relative to the translation piece,” *i.e.*, the drive member reciprocates, not the translation piece.

S&N's argument that "the claimed translation piece cannot be a 'non-reciprocating piece of the drive' without reading limitations" out of the claim (*id.*) should be rejected.

S&N admits that "some embodiments of the invention may include a translation piece that remains stationary relative to some other drive component." (*Id.* p. 17.) In fact, all of the embodiments described in the specification are of a translation piece that does not reciprocate. (Ex. A col. 3:31-34; 4:18-22; 4:23-31; 4:36-43.) There is no disclosure in the specification that the translation piece may axially translate or otherwise reciprocate.

The prosecution history and the testimony from the inventors and prosecuting attorney also support Interlace's construction. For example, in the Notice of Allowance, the examiner stated that "[n]one of the prior art of record, alone or in combination, discloses a surgical instrument with . . . a translation piece *for reciprocation of the drive member* relative to the translation piece." (Ex. N pp. 2-3.) Thus, the Examiner expressly noted that the translation piece causes *reciprocation of the drive member*, not, as argued by S&N, that the translation piece reciprocates. The prosecuting attorney, Ms. DiBerardino, similarly confirmed at her deposition that "

" (Ex. E at 143:7-14; 140:24-141:11.) Mr. Cesarini

stated that in the '459 patent

The other aspects of Interlace's construction – that the translation piece is a "piece of the drive that provides for translation of the cutting member" – are also supported by the intrinsic evidence. The specification provides that "the helical member 150 and a translation piece 145 are coupled together such that rotation of the helical member 150 causes linear translation of the helical member 150" and that "[t]he helical member 150 also moves in an axial direction, e.g., reciprocates, as a result of the interaction of the translation piece 145 with the helical channels 156, 158." (Ex. A at 3:31-34; 4:19-22.)

S&N’s proposed construction improperly mixes different limitations from different claim elements. For example, nothing in the claim language indicates that the translation piece term “enables simultaneous reciprocation, translation, and rotation of the drive member” as proposed by S&N. (*See* Ex. A claim 1.) Rather, the preceding limitation in claim 1 provides that it is the *drive* that simultaneously rotates, translates, and reciprocates the cutting member, not the translation piece. The claim requires that the translation piece causes the drive member to reciprocate. (*See id.*) Further, S&N’s proposed requirement that the translation piece is “located at least in part in a helical groove” is an inappropriate paraphrasing of other language in the claim requiring that the translation piece is “disposed in the groove....”

Unlike S&N proposal, Interlace’s proposed construction is based on the plain meaning of “translation piece,” the context of the surrounding claim language, the specification, file history, and inventor testimony.

#### **E. “coupled”**

<b>Interlace’s Proposed Claim Construction</b>	<b>S&amp;N’s Proposed Claim Construction</b>
“linked, joined, or connected”	“a connection in which one component influences motion of a second component, without necessarily constraining any degree of freedom of the second component”

The parties are not far apart in their proposed constructions of “coupled.” Interlace proposes a simple construction that comports with the plain meaning of the term in view of the intrinsic evidence. S&N admits that “Interlace’s proposed construction is not necessarily inaccurate.” S&N proposes extra language that is not supported by the plain meaning of “coupled” or the intrinsic evidence. Moreover, S&N’s proposed construction is difficult to understand, and it would be difficult for the jury to apply that construction in this case.

One of the most popular dictionaries today – [www.dictionary.com](http://www.dictionary.com) – defines “coupled” as “to fasten, link, or associate together in a pair or pairs; to join; connect.” (Ex. Q.) The dictionaries cited by S&N support this meaning. (S&N’s Br. at 14-15.) Moreover, Interlace’s proposed construction has been adopted by the Federal Circuit. *See Bradford Co. v. Conteyor N.*

*Am., Inc.*, 603 F.3d 1262, 1265 (Fed. Cir. 2010) (construing “coupled to” to mean “linked together, connected or joined.”); *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1258 (Fed. Cir. 2007) (“The term ‘coupled to’ in the phrase ‘second stage input terminal “coupled to” the first stage output terminal’ defines **a connection** between the TGMs.”). There is no basis to deviate from the established meaning of “coupled” as “linked, joined, or connected.”

**F. “arched bridge shape”**

<b>Interlace’s Proposed Claim Construction</b>	<b>S&amp;N’s Proposed Claim Construction</b>
“a curved, concave shape”	“a shape in which two legs are connected by a curved concave portion”

The parties’ proposed constructions are not far apart. Interlace does not dispute the “curved concave shape” part of S&N’s construction, but the requirement of “two legs” being “connected” adds ambiguity and makes S&N’s proposed construction unintelligible. There is no plain meaning of “legs” in the context of the follower piece in the specification, which is described as having an arched bridge shape. While the term “legs” is used with respect to the embodiment shown in the figures of the ‘459 patent, there is no basis for importing such a vague “legs” requirement into the claim term. In addition, the term “connected” is vague, especially in light of the parties’ disputes regarding the meaning of “coupled” and “attached.” Neither of these extra terms is supported by the specification or prosecution history.

**G. “chamfered cutting edge”**

<b>Interlace’s Proposed Claim Construction</b>	<b>Plaintiff’s Proposed Claim Construction</b>
“a cutting edge that has been sharpened for cutting tissue”	“a sloping face of a cutting element”

Interlace can agree to S&N’s proposed construction of “chamfered cutting edge” as “a sloping face of a cutting element, so long as it is understood that the “sloping face” is the part of the cutting element that cuts. This is required by the language “cutting edge” in the claim.



Dated: October 27, 2010

**INTERLACE MEDICAL, INC.,**

By its attorneys,

/s/ Joel R. Leeman

Joel R. Leeman, BBO # 292070

Jack C. Schechter, BBO # 652349

SUNSTEIN KANN MURPHY

& TIMBERS LLP

125 Summer Street

Boston, MA 02110-1618

Tel: 617-692-2281

Email: [jleeman@sunsteinlaw.com](mailto:jleeman@sunsteinlaw.com)

*Pro hac vice (pending):*

Matthew M. Wolf

Marc A. Cohn

HOWREY LLP

1299 Pennsylvania Ave, NW

Washington, DC 20004

Tel: 202-783-0800

**CERTIFICATE OF SERVICE**

I certify that, on the above date, this document and its exhibits contemporaneously filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Joel R. Leeman